**APPROVAL LETTER**

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| This is to certify that the following protocol and related documents have been reviewed and is hereby granted approval by the FNRI Institutional Ethics Review Committee for implementation. |

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| **FIERC PROTOCOL CODE** | Click or tap here to enter text. | **DATE SUBMITTED** | Click or tap to enter a date. |

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| **PROTOCOL TITLE** | Click or tap here to enter text. |

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| **PRINCIPAL INVESTIGATOR/S** | Click or tap here to enter text. | **SPONSOR / FUNDING AGENCY** | Click or tap here to enter text. |

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| **PROTOCOL VERSION NUMBER** | Click or tap here to enter text. | **PROTOCOL VERSION DATE** | Click or tap to enter a date. |

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| **ICF VERSION NUMBER** | Click or tap here to enter text. | **ICF VERSION DATE** | Click or tap to enter a date. |

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| **TYPE OF REVIEW** | [ ]  **EXPEDITED** | [ ]  **FULL BOARD (MEETING DATE:** Click or tap to enter a date.**)** |

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| **APPROVAL DATE:**  | Click or tap to enter a date. | **EXPIRY OF ETHICAL CLEARANCE :** | Click or tap to enter a date. |

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| **DUE DATE OF APPLICATION FOR RENEWAL OF ETHICAL CLEARANCE (30 days before expiry):** | Click or tap to enter a date. | **FREQUENCY OF PROGRESS REPORT:** |
| Frequency as decided by the FIERC based on the level of risks |

**APPROVED BY:**

 **Click or tap here to enter text.**

 **FIERC Chair**

Click or tap to enter a date.

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| **Principal Investigator Responsibilities after Approval:*** Submit document amendments for FIERC approval before implementing them
* Submit revisions in the protocol and Informed Consent Form using **Form 09-01 v.2 Protocol Amendment Report**
* Submit Reportable Negative Event reports at least three (3) days after the event has come to the attention of the researcher.
* Submit Serious Adverse Event (SAE) and Suspected Unexpected Serious Adverse Reaction (SUSAR) reports to the FIERC within seven (7) days
* Submit progress report 3 months after the approval and every 3 months thereafter
* Submit continuing review application at least one (1) month prior to expiration date.
* Submit final report/summarized terminal report not later than 8 weeks after completion of research
* Report protocol non-compliance / deviation/violation
* Comply with all relevant international and national guidelines and regulations
* Abide by the principles of good clinical practice and ethical research
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 **Conforme:**

 **Click or tap here to enter text.**

 **Principal Investigator**

 **Received by:**

 **Click or tap here to enter text.**

 **Signature over Printed Name**

Click or tap to enter a date.